REMARKS

Claims 14-37 are pending in the instant application. Claims 14-37 have been rejected. Claims 14 and 28 has been amended. Claims 15-20 and 29-34 have been canceled. New claims 38 through 49 have been added. Support for these amendments is provided in the specification at page 7, lines 10-12 and 27-29, page 15, lines 7-9 and in canceled claims 18, 19, 32 and 33. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Objection to Claim 14

Claim 14 has been objected to for appearance of the term "a" before "polynucleotide sequences". Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have deleted the term --a--. Withdrawal of this objection is therefore respectfully requested.

II. Rejection of Claims 14-37 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph - Lack of Utility

Claims 14-37 have been rejected under 35 U.S.C. 101 because the Examiner suggests that the claimed invention is not supported by either a substantial asserted utility or a well established utility. These claims have also been rejected under 35 U.S.C. 112, first paragraph, because the Examiner suggests that without support of a substantial

asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Arguments presented by Applicants in the last response were suggested by the Examiner not to be persuasive as the Examiner suggests that the art of Tringler and Salceda are post filing references and although they might demonstrate the protein encoded from SEQ ID NO:1 is expressed in cancer and detected with an antibody, the specification as filed did not teach the protein sequence or the open reading frame of SEQ ID NO:1. Thus, the Examiner suggests that there was no indication in the specification that the protein was expressed or even what the protein was and therefore one would not have known a utility for such a protein or how to use such an antibody directed to such.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the claims 14 and 28 have been amended and are now drawn to an isolated antibody or antibody fragment and methods of using an isolated antibody or antibody fragment that binds specifically to a protein encoded by polynucleotide sequence SEQ ID NO:1.

With respect to this rejection under 35 U.S.C. 101, MPEP 2107.02 and the case law is clear,

> as a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be

> patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d 1380, 1391, 183 USPQ 228, 297 (CCPA 1974)(emphasis in original)

Utility of the claimed invention is set forth in detail in teachings of the original, as-filed specification at page 6, lines 3 through 20, page 11, line 5 through page 12, line 7, and page 14, line 5 through page 15, line 27.

Further, compliance with 35 U.S.C. 101 is a question of fact. Raytheon v. Roper, 724 F.2d 951,956, 220 USPQ 592, 596 (Fed. Cir. 1983, cert denied, 469 U.S. 835 (1984). Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, Office personnel must establish that it is more likely than not that one or ordinary skill in the art would doubt (i.e. "question") the truth of the statement of utility. To do this, Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. MPEP 2107.02.

No such evidence that the statement of asserted utility for the instant claimed invention would be considered false by the skilled has been provided by the Examiner in the instant case.

In contrast, Applicants have provided confirming evidence which demonstrates the fact that the claimed

invention is useful in the manner taught in the originally filed application. See references by Tringler and Salceda submitted by Applicants in the response filed May 3, 2005.

Thus, further maintenance of this rejection under 35 U.S.C. 101 for lack of utility is improper and withdrawal of this rejection under 35 U.S.C. 101 is respectfully requested.

Further, the test of enablement is whether one reasonably skilled in the art could make or use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. See MPEP 2164.01. Thus, the test of enablement is not whether any experimentation is necessary but whether, if experimentation is necessary it is undue. In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). If the art typically engages in such experimentation, it is not considered undue. See In re Certain Limited-Charge Cell Culture Microcarriers, 221 USPQ 1165, 1174 ((Int'l Trade Comm'n 1983), aff'd sub nom., Massachusetts Institute of Technology v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Applicants are submitting herewith a Declaration by Dr. Susana Salceda which makes clear that any experimentation necessary to make and use the invention as claimed was routine to the skilled artisan when coupled with the

information taught in the specification. As discussed in detail in paragraph 6 of Dr. Salceda's Declaration, protein sequences and/or open reading frames were routinely obtained by those skilled in the art at the time of filing the instant patent application based upon information such as provided in the instant specification. In particular, the specification teaches in Examples 1 and 2 that SEQ ID NO:1 is an mRNA molecule and thus has a set 5' to 3' orientation. See in particular pages 16-18 of the instant specification. From this information, Dr. Salceda advises that one skilled in the art would know that the protein is encoded in the forward (5' to 3') direction of SEQ ID NO:1. See paragraph 6 of Dr. Salceda's Declaration. This characteristic taught in the originally filed specification limits the potential frame translations to three possibilities. Further, Dr. Salceda advises that the skilled artisan would know that the open reading frame would be the frame of SEQ ID NO:1 encoding for a methionine near the 5' end, encoding many amino acids and would be terminating with a stop codon. See paragraph 6 of Dr. Salceda's Declaration. Thus, according to Dr. Salceda, any frame with multiple stop codons could be ruled out. See paragraph 6 of Dr. Salceda's Declaration. As also made clear in paragraph 6 of Dr. Salceda's Declaration, multiple tools were available by 1998, thus preceding the September 2, 1998 priority date of the instant

application, which could be used to routinely determine the protein sequence and/or open reading frame of SEQ ID NO:1 based upon the information provided in the instant specification. The examples provided in Dr. Salceda's Declaration are results from three different computer programs available to those skilled in the art as of the filing date of the instant application. Quite clear in these Figures is the fact that for this particular nucleic acid sequence, SEQ ID NO:1, there was only one possible frame for a full length protein, frame 2, with a methionine near the 5' end, encoding a protein many amino acids in length and terminating with a stop codon. Thus, as can be seen in the Figures of Dr. Salceda's Declaration, the results of which are described in detail in paragraph 6 of Dr. Salceda's Declaration, using only the information disclosed in the instant specification, each of these programs was able to identify the open reading frame and protein encoded by SEQ ID NO:1. Clearly, this simple step required to identify the open reading frame and protein encoded by SEQ ID NO:1 using the characteristics of SEQ ID NO:1 taught in the instant specification does not constitute undue experimentation.

Also well known and routine to those of skill in the art at the time of filing the instant application were methods for expressing proteins encoded by a nucleotide

sequence such as SEQ ID NO:1 and generating antibodies thereto. See paragraph 8 of Dr. Salceda's Declaration.

Further, contrary to the Examiner's suggestion, detailed guidance for the skilled artisan to use the instant invention is provided in teachings throughout the specification. As discussed in paragraph 10 of Dr. Salceda's Declaration, teachings in Examples 1 and 2 relating to mRNA overexpression of Ovr110 are demonstrative to the skilled artisan of its utility as a diagnostic marker for gynecologic cancers. Further, uses for the protein encoded by SEQ ID NO:1 and antibodies against Cancer Specific Genes such as SEQ ID NO:1 are described in detail in the specification, for example at pages 11-12 and 14-15 of the instant application. Also see paragraph 10 of Dr. Salceda's Declaration.

Thus, contrary to the Examiner's suggestion, the teachings of the instant specification are not merely "starting points for further research and investigation into potential practical uses", but rather provide adequate disclosure when coupled with information known to those skilled in the art to make and use the invention as claimed. Information well known in the art does not need to be described in detail in the specification. MPEP 2163 at page 2100-170 and Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

Accordingly, the instant specification meets the enablement requirements of 35 U.S.C. 112, first paragraph as well. See MPEP 2164.01. Withdrawal of this rejection is therefore respectfully requested.

III. Rejection of Claims 14-37 under 35 U.S.C. 112, first paragraph - Written Description

Claims 14-37 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirements. The Examiner suggests that Applicants were not in possession of any protein encoded by SEQ ID NO:1, or just any fragments of SEQ ID NO:1, 10-13 or 16.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the claims 14 and 28 have been amended and are now drawn to an isolated antibody or antibody fragment and methods of using an isolated antibody or antibody fragment that binds specifically to a protein encoded by polynucleotide sequence SEQ ID NO:1. Claims to fragments have been amended to be drawn to SEQ ID NO:12 and 13.

Antibodies and methods of their use were described in detail and claimed in the original, as-filed specification. See teachings at pages 6, 11-12 and 14-15 as well as claims 9 through 13 of the specification as-filed. Further, native

protein and methods for detection thereof are described in the original, as-filed application at pages 7 and 11-12.

The MPEP and case law are clear; "the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." MPEP 2163 at page 2100-166; In re Wertheim, 541 F.2d 257 at 263, 191 USPQ 90 at 97 (CCPA 1976). Moreover, if the skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description is met. Also see Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Possession may be shown in a variety ways including describing distinguishing identifying characteristics to show that applicants was in possession of the claimed invention. See MPEP 2163. Precisely how close [to the claimed invention] the description must come to comply with § 112 must be left to case-by-case-development. In re Wertheim, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of the knowledge imparted to those skilled in the art by the disclosure). Whether the specification shows that applicant was in possession of the claimed invention is

not a single, simple determination, but rather a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. See MPEP 2163 at page 2100-73 and Regents of the University of California v. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 (Fed. Cir. 1997). Patents and printed publications in that art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. See, e.g. In re Hayes Microcomputer Products, Inc. Patent Litigation, 982 F.2d 1527, 1534-1535, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992).

As already discussed in detail in Section II, supra, Applicants are providing herein a Declaration by Dr. Susana Salceda's which makes clear that while every nuance of the protein sequence and/or open reading frame of SEQ ID NO:1 may not have been explicitly described in the specification, sufficient distinguishing characteristics were taught in the specification so that using standard tools available to those skilled in the art as of the filing date of the instant application this information could be routinely determined. See specifically paragraph 11 of Dr. Salceda's Declaration. Also see paragraph 6 of Dr. Salceda's Declaration wherein she describes available tools for routinely obtaining the protein sequence and open reading frame based upon the distinguishing characteristics of SEQ ID NO:1 taught in the instant application. Further, see the Figures of Dr. Salceda's Declaration wherein she demonstrates specific use of these tools to identify the protein sequence and open reading frame of SEQ ID NO:1 based only upon the distinguishing characteristics of SEQ ID NO:1 taught in the instant specification.

Clear from Dr. Salceda's Declaration is the fact that is based upon the distinguishing characteristics taught for SEQ ID NO:1 in the originally filed specification, one of skill understood that there were only 3 possible frames to examine for the coding region. Further, clear from the

Figures provided with Dr. Salceda's Declaration is the fact that for this particular nucleic acid sequence, SEQ ID NO:1, there was only one possible frame, frame 2, with a methionine near the 5' end, encoding many amino acids and terminating with a stop codon. Thus, the factors in this particular case demonstrate the disclosure in the instant specification of a combination of identifying characteristics that distinguish the instant claimed invention from other materials, thereby leading one of skill in the art to the conclusion that the applicant was in possession of the claimed species.

Also supportive of this conclusion are the printed publications provided with Dr. Salceda's Declaration showing that the art describing tools for identification of the open reading frame of a nucleic acid sequence such as SEQ ID NO:1 was mature at the time of filing the instant application. References provided therewith date back as far as 1984. Thus, clearly the knowledge and level of skill in the art is high. Therefore a written description question should not be raised for original claims given that the specification discloses a method of making the claimed invention and a function of the invention. See MPEP 2163 and In re Hayes 982 F.2d at 1534-1535, 25 USPQ2d at 1246.

Further, as made clear by MPEP 2163 at page 2100-169, col. 2, the "absence of definitions or details for well-

established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, paragraph 1, for lack of written description." As demonstrated by Dr. Salceda's Declaration, determination of the coding region of SEQ ID NO:1 and the encoded protein was determined using well-established procedures. Accordingly, absence of details of this coding region or the encoded protein in the instant specification should not be the basis of a rejection under 35 U.S.C. 112, first paragraph, for lack of written description.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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